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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,481	10/03/2003	Randall S. Hickle	82021-0046	4577

24633 7590 05/18/2006

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EXAMINER	
SUNDARARAMAN, VIKRAM P	
ART UNIT	**PAPER NUMBER**
3735	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

6

Office Action Summary	Application No.	Applicant(s)
	10/677,481	HICKLE, RANDALL S.
	Examiner	**Art Unit**
	Vikram P. Sundararaman	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-10, 12-18, and 20** are rejected under 35 U.S.C. 102(b) as being anticipated by Tavori, US 5,724,025, hereinafter referred to as "Tavori."

3. As to **Claim 1**, Tavori teaches, ***a patient monitoring system:*** "Portable vital signs monitor," [Title] that includes:

a. ***A first patient health monitor device:*** "sensor, 28" [Column 9, Line 15] ***adapted so as to be coupled to a patient and so as to generate a first signal reflecting a first parameter of a physiological condition of the patient:*** "The device includes a substantial base with at least two electrodes which forms a means for mounting a plurality of sensors in contact with measured body." [Column 3, Lines 65-67];

b. ***A second patient health monitor device:*** "sensor, 29" [Column 9, Line 17] ***adapted so as to be coupled to a patient and so as to generate a first signal reflecting a first parameter of a physiological condition of the patient:*** "The device includes a substantial base with at least two electrodes which forms a means for mounting a plurality of sensors in contact with measured body." [Column 3, Lines 65-67]; ***wherein said first parameter and said second parameter are related;***

c. ***A memory device storing a safety data set reflecting safe and undesirable parameters for each of said first and second physiological conditions:*** "The electrical circuit has data storage capability to store outputs coming from various sensors," [Column 3, Lines 51-53], "Memory with data storage capability, 44, which can be realized as Flash memory, available from Intel corporation, as a dynamic random-access-memory (D-RAM) or static random-access-memory (S-RAM), available from other leading manufacturers, or other memory systems," [Column 4, Lines 58-62] and "Controller, 45, compares measured data of sensor, 35, to normal, upper, and lower values, 55, 56, and 57, respectively." [Column 7, Lines 32-33];

d. ***An electronic controller interconnected with said first and second patient health monitors and said memory device, wherein the electronic controller compares said first and second parameters with said safety data***

set so as to initiate a response upon detection of undesirable signals from both of said first and second patient health monitor devices: "The device includes communication means which allow data transfer of stored data or on-line measured data to an inquiring system, and which permit operator download measuring logics and sequence and the changing set-point or set-points of the alarm device," [Column 3, Lines 58-62], "Communication means, 13, for example, an RS-232 interface which is used to send and receive data and instruction sets; and, Alarm device, 23, which may be an annunciator, for providing audible warning to notify that an event had occurred. The RS-232 interface may be realized by any of many industry-standard integrated circuits which perform this function, such as the LT1133," [Column 4, Line 64 – Column 5, Line 3], and "Data accumulated in device 10 can be used to build a database of measured parameters of a monitored body. The managing physician may wish to use a medical diagnostic program such MEDICAL DOCTOR which is available from PIXEL PERFECT CORPORATION, Florida, and integrate measured parameters into a diagnostic module which can be installed in inquiring system 24 or 40." [Column 8, Lines 15-21]

4. As to **Claim 2**, Tavori teaches, ***wherein said first and second patient health monitoring devices are each independently selected from the group consisting of non-invasive blood pressure monitors, pulse oximeters, capnometers, ECGs, ... acoustical monitors:*** "Numerous monitoring and/or measuring devices are

commercially available. These include thermometers which save the last ten readings, portable ECG monitors, hand-held blood pressure measurement devices, and even a wristwatch which measures and stores pulse rate and blood pressure. All the above-mentioned devices are expensive and are dedicated to certain measurements which are electronically implemented during manufacturing stage. These devices either do not allow the managing physician to retrieve accumulated historical data by electronic means, or strictly limit his ability to do so. In addition, the devices do not allow the physician to focus on particular data of interest," [Column 1, Lines 45-56] and "present systems do not allow the combination of the readings of several sensors so as to form a more definitive diagnosis." [Column 2, Lines 5-7] It is understood then that the patient health monitoring devices taught by Tavori includes by non-limiting example: non-invasive blood pressure monitors, ECGs, pulse rate monitors, and temperature monitors.

5. As to **Claim 3**, Tavori teaches, ***wherein said response comprises at least alarming:*** "Alarm device, 23, which may be an annunciator for providing audible warning to notify that an event had occurred," [Column 4, Lines 66-67+] wherein "an event is defined as a monitored combination of measured parameters exceeding a set-point limit, indicating a possible need for medical attention or consultation." [Column 5, Lines 10-12]

6. As to **Claim 4**, Tavori teaches, ***wherein said memory device stores a safety data set for a third patient parameter and wherein said electronic controller further comprises using the monitored data for the first patient parameter and the second patient parameter to calculate said third patient parameter that is compared against said safety data et for said third patient parameter:*** "Operating parameters include… the expected normal values, 55, the upper limit of the signal, 56, the lower limit, 57, and at least one value such as delta, 58, which has a value depending on normal value, 55, and the upper/lower limits, 56 and 57, respectively. Delta can take the form of a simple value or may be a mathematical equation." [Column 6, Line 65 – Column 7, Line 3] It is understood therefore that since normal values, and upper and lower limits can be defined as a data set for each sensor, that a mathematical equation defining a "delta, 58," value can be used to define a third safety data set. Furthermore it "includes logical IF, IF-THEN, AND, OR, NOR, NOT, and similar instructions allowing a combination of several sensor's output to be concluded into one conclusion." [Column 7, Lines 14-17] In this way the controller, 45, as previously described in this action is able to use a single sensor signal or a combination of sensor signals and compare it against the data set for a third patient parameter. Furthermore, "a set-point can be defined by combining data coming from various sensors, even when data coming from any individual sensor is below the preset set-point for that individual sensor. This makes it possible to use a combination of sensors to create an alarm which would not have been produced were each sensor monitored alone independently of the others." [Column 8, Lines 59-65] with the use of logic

controls, it is noted that, “this way a combination of several sensor outputs, each not exceeding upper or lower limit setup, but which, in combination, do exceed normal value plus delta, may be combined in to significant result.” [Column 7, Lines 53-57]

7. As to **Claim 5**, Tavori teaches, ***a method employing sensor fusion in a patient monitoring system comprising:***

> **e.** ***Providing at least one patient monitor corresponding to a first patient parameter and at least one patient monitor corresponding to a second patient parameter:*** “Portable vital signs monitor unit, 10,” [Column 5, Line 4] with “four sensors... represented, 28, 29, 30, and 31” [Column 9, Lines 13-14], wherein, “The device includes a substantial base with at least two electrodes which forms a means for mounting a plurality of sensors in contact with measured body.” [Column 3, Lines 65-67]; ***wherein said parameters are interrelated and each of said monitors provide data:*** It is understood that since a monitor or a plurality of monitors all sense physiological data, that they are interrelated. Furthermore, “measurements are taken continuously or intermittently as present by the operating software. The data are either continuously or intermittently transmitted...” [Column 2, Lines 63-65]

f. ***Monitoring at least two of said interrelated parameters:*** "An event is defined as a monitored combination of measured parameters," [Column 5, Line 10];

g. ***Ascertaining whether any of said data is indicative of a negative patient episode:*** "a monitored combination of measured parameters exceeding a set-point limit, indicating possible need for medical attention or consultation." [Column 5, lines 10-12];

h. ***Determining whether there is agreement between each monitor:*** "If we write logical operations as capital letters with periods on either side, then for example, we might have, '.IF. sensor 35 signal .AND. sensor 36 signal is .GREATER THAN. (a specified value) .EQUALS. .TRUE. .THEN. an event is defined to have occurred and a warning alarm indication is given'" [Column 7, Lines 17-22] Also, "Further, more than one portable vital signs monitor unit, 10, of the present invention may be located on the patient, in which case the RS-232 interface may be used to provide communication between the monitor units." [Column 5, Lines 3-7]; In this way, following the example of logical operations given above, only if both monitors/sensors have a signal greater than a value, is agreement considered applicable, and only then is an even considered and having happened and only therefore is a warning alarm given; and *i.* ***Initiating a suitable procedure in response to said data indicative of negative patient episode:*** "providing audible warning to notify that an event had occurred." [Column 4, Line 67]

8. As to **Claim 6**, Tavori teaches, ***wherein step of ascertaining further comprises comparing said data from each of the monitors against a safety data set:*** "Operating parameters include... the expected normal values, 55, the upper limit of the signal, 56, the lower limit, 57, and at least one value such as delta, 58, which has a value depending on normal value, 55, and the upper/lower limits, 56 and 57, respectively." [Column 6, Lines 65 - 67]

9. As to **Claim 7**, Tavori teaches, ***wherein said suitable procedure comprises at least on of alarming...delivering positive airway pressure:*** "providing audible warning to notify that an event had occurred." [Column 4, Line 67]

10. As to **Claim 8**, Tavori teaches, ***wherein step of determining whether there is agreement between each monitor comprises comparing data from each of said monitors with a respective data set:*** "The device includes communication means which allow data transfer of stored data or on-line measured data to an inquiring system, and which permit operator download measuring logics and sequence and the changing set-point or set-points of the alarm device," [Column 3, Lines 58-62], "Communication means, 13, for example, an RS-232 interface which is used to send and receive data and instruction sets; and, Alarm device, 23, which may be an annunciator, for providing audible warning to notify that an event had occurred. The RS-232 interface may be realized by any of many industry-standard integrated circuits which perform this function, such as the LT1133." [Column 4, Line 64 – Column 5, Line 3]

11. As to **Claim 9**, Tavori teaches, ***wherein said step of determining whether there is agreement between each monitor further comprises evaluating the relationship between said data for monitored parameters that fall within said safety data set:*** "In FIG 3B, there are several graphs indicating the representation of instructions, data, and results of the device, 10. The graphs in FIG 3b may be interpreted in several ways. As a non-limiting example, one of the graphs may represent an actual sensor readout, its normal value, 55, delta, 58, upper limit, 56, and lower limit, 57." [Column 7, Lines 58-64] It is understood that producing a graph is a way to evaluate relationship between data.

12. As to **Claim 10**, Tavori teaches, ***continuing to gather data from the monitors for a predetermined period of time before said suitable procedure is initiated:*** "Data accumulated in device, 10, can be used to build a database of measured parameters of a monitored body." [Column 8, Lines 15-16] Furthermore, "In case a specific focusing on data collection or measurement is needed, a managing physician can express his point of interest via the communication means 13, so device 10 will perform tasks indicated. Furthermore, alarm set-points can be defined, such that when one or more pre-defined set-points or combination of set-points are exceeded an alarm will be given by an alarm device 23." [Column 8, Lines 51-54]

13. As to **Claims 12 and 13**, Tavori teaches, ***the step of using the monitored data for the first patient parameter and the second patient parameter to calculate a third patient parameter:*** "includes logical IF, IF-THEN, AND, OR, NOR, NOT, and similar instructions allowing a combination of several sensor's output to be concluded into one conclusion." [Column 7, Lines 14-17]

14. As to **Claim 14**, Tavori teaches, ***a method employing sensor fusion in a patient monitoring system comprising:***

> **j.** ***Providing at least one patient monitor corresponding to a first patient parameter and at least one patient monitor corresponding to a second patient parameter:*** "Portable vital signs monitor unit, 10," [Column 5, Line 4] with "four sensors... represented, 28, 29, 30, and 31" [Column 9, Lines 13-14], wherein, "The device includes a substantial base with at least two electrodes which forms a means for mounting a plurality of sensors in contact with measured body." [Column 3, Lines 65-67]; ***wherein said parameters are interrelated and each of said monitors provide data:*** It is understood that since a monitor or a plurality of monitors sense physiological data, that they are

interrelated. Furthermore, "measurements are taken continuously or intermittently as present by the operating software. The data are either continuously or intermittently transmitted..." [Column 2, Lines 63-65]

k. ***Monitoring at least two of said interrelated parameters:*** "An event is defined as a monitored combination of measured parameters," [Column 5, Line 10];

l. ***Ascertaining whether that data from any of said monitors is conclusive of a potentially critical condition***: "a monitored combination of measured parameters exceeding a set-point limit, indicating possible need for medical attention or consultation." [Column 5, lines 10-12];

m. ***If data is inconclusive, analyzing the data from said first and second patient parameters to determine whether one monitor can confirm the potentially critical condition indicated by at least one other monitor:*** A potentially critical condition is assessed when a signal from a sensor is outside of an upper and lower limit defined by normal values and a delta for each sensor. If a signal is not outside of the upper or lower limit, it is inconclusive. Similarly if a second signal is also not outside of an upper or lower limit it is inconclusive. Tavori teaches, "a combination of several sensor outputs, each not exceeding upper or lower limit setup, but, in combination, do exceed normal value plus delta, may be combined into significant result." [Column 7, Lines, 53-57] In this way one monitor can confirm a potentially critical condition indicated by another monitor; and

n. ***Initiating a suitable procedure in response to said data indicative of negative patient episode:*** "providing audible warning to notify that an event had occurred." [Column 4, Line 67]

15. As to **Claim 15**, Tavori teaches, ***wherein said data is processed by a controller:*** "Controller, 45, compares measured data of sensor, 35." [Column 7, Line 31]

16. As to **Claim 16**, Tavori teaches, ***the step of ascertaining whether the clarified data is indicative of a negative patient condition based on safe data set programmed into the controller:*** "Logical gates, step 52, includes logical IF, IF-THEN, AND, OR, NOR, NOT, and similar instructions allowing a combination of several sensor's output to be concluded into one conclusion." Furthermore, "If we write logical operations as capital letters with periods on either side, then, for example, we might have, '.IF. sensor, 35, signal .AND. sensor, 36, signal is .GREATER THAN. (a specified limit value), .EQUALS. TRUE. .THEN. an event is defined to have occurred, and a warning alarm indication is given.'" [Column 7, Lines 17-26]

17. As to **Claim 17**, Tavori teaches, ***wherein said suitable procedure comprises at least one of alarming... delivering positive airway pressure:*** "providing audible warning to notify that an event had occurred." [Column 4, Line 67]

18. As to **Claim 18**, Tavori teaches, ***wherein said alarming procedure comprising providing different alarming modes that vary depending on whether the data inconclusively or conclusively indicates the potentially critical condition:*** "combinations of test limits, based on which logical decisions will be made concerning whether to sound a warning alarm, and which severity of warning alarm indication is to be given," [Column 5, Lines 24-24] and "Alarm device, 23, can be realized as an audio alarm such as a speaker or piezo-electric buzzer, for example. Alarm device, 23, may be used to generate various audible signals of different rates and/or pitches corresponding to the detected condition of the monitored body." [Column 5, Line 65-Column 6, Line 2]

19. As to **Claim 20**, Tavori teaches, ***the step of using the monitored data for the first patient parameter and the second patient parameter to calculate a third patient parameter:*** "includes logical IF, IF-THEN, AND, OR, NOR, NOT, and similar instructions allowing a combination of several sensor's output to be concluded into one conclusion." [Column 7, Lines 14-17]

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. **Claim 11** is rejected under U.S.C. 103(a) as being unpatentable over Tavori in view of Nielsen et al., US 2003/0120164 A1, hereinafter referred to as "Nielsen." Tavori teaches the method as described by the limitations in Claim 5 as described previously in this action. What it does not teach is, ***wherein said first patient parameter comprises electric heart activity and said second patient parameter comprises pulse oximetry.*** Tavori teaches measuring multiple vital signs, but not specifically electrical heart activity and pulse oximetry. Nielsen teaches that it is well known to monitor electrical heart activity and pulse oximetry together in a vital signs monitor. [Paragraph 0031] Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention, to modify the teachings of Tavori to include the combination of measured parameters (electrical heart activity and pulse oximetry) of Nielsen, in order to accommodate the sensing of various vital signs and physiological parameters as needed by different patient populations for different circumstances.

22. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Tavori in view of Daniels et al., 6,099,481, hereinafter referred to as "Daniels." Tavori teaches the method as described by the limitations in Claim 14 as described previously in this action. What Tavori does not teach is, ***wherein said first patient parameter comprises capnometry and said second patient parameter comprises ventilatory pressure.*** Tavori teaches measuring multiple vital signs, but not specifically capnometry and ventilatory pressure. Daniels teaches that it is well known to monitor capnometry and ventilatory pressure. [Column 1, Lines 7-9 & FIG 1] Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention, to modify the teachings of Tavori to include the combination of measured parameters (capnometric and ventilatory pressure) of Daniels, in order to accommodate the sensing of various vital signs and physiological parameters as needed by different patient populations for different circumstances.

23. **Claim 21** is rejected under U.S.C. 103(a) as being unpatentable over Tavori in view of Nielsen. Tavori teaches the method as described by the limitations in Claim 5 as described previously in this action. What does not teach is, ***wherein said first patient parameter comprises electric heart activity and said second patient parameter comprises pulse oximetry.*** Tavori teaches measuring multiple vital signs, but not specifically blood pressure data and pulse oximetry. Nielsen teaches that it is well known to monitor blood pressure and pulse oximetry together in a vital signs monitor. [Paragraph 0031] Therefore, it would have been obvious to one with ordinary

skill in the art at the time of the invention, to modify the teachings of Tavori to include the combination of measured parameters (electrical heart activity and pulse oximetry) of Nielsen, in order to accommodate the sensing of various vital signs and physiological parameters as needed by different patient populations for different circumstances.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vikram P. Sundararaman whose telephone number is 571-272-3351. The examiner can normally be reached on M-F, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A Marmor, II
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VPS